

§ 862.1300

(b) *Classification*. Class II.

[52 FR 16122, May 1, 1987; 53 FR 11645, Apr. 8, 1988]

§ 862.1300 Follicle-stimulating hormone test system.

(a) *Identification*. A follicle-stimulating hormone test system is a device intended to measure follicle-stimulating hormone (FSH) in plasma, serum, and urine. FSH measurements are used in the diagnosis and treatment of pituitary gland and gonadal disorders.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2306, Jan. 14, 2000]

§ 862.1305 Formiminoglutamic acid (FIGLU) test system.

(a) *Identification*. A formiminoglutamic acid (FIGLU) test system is a device intended to measure formiminolutamic acid in urine. FIGLU measurements obtained by this device are used in the diagnosis of anemias, such as pernicious anemia and congenital hemolytic anemia.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988; 66 FR 38787, July 25, 2001]

§ 862.1310 Galactose test system.

(a) *Identification*. A galactose test system is a device intended to measure galactose in blood and urine. Galactose measurements are used in the diagnosis and treatment of the hereditary disease galactosemia (a disorder of galactose metabolism) in infants.

(b) *Classification*. Class I.

§ 862.1315 Galactose-1-phosphate uridyl transferase test system.

(a) *Identification*. A galactose-1-phosphate uridyl transferase test system is a device intended to measure the activity of the enzyme galactose-1-phosphate uridyl transferase in

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erythrocytes (red blood cells). Measurements of galactose-1-phosphate uridyl transferase are used in the diagnosis and treatment of the hereditary disease galactosemia (disorder of galactose metabolism) in infants.

(b) *Classification*. Class II.

§ 862.1320 Gastric acidity test system.

(a) *Identification*. A gastric acidity test system is a device intended to measure the acidity of gastric fluid. Measurements of gastric acidity are used in the diagnosis and treatment of patients with peptic ulcer, Zollinger-Ellison syndrome (peptic ulcer due to gastrin-secreting tumor of the pancreas), and related gastric disorders.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988; 66 FR 38787, July 25, 2001]

§ 862.1325 Gastrin test system.

(a) *Identification*. A gastrin test system is a device intended to measure the hormone gastrin in plasma and serum. Measurements of gastrin are used in the diagnosis and treatment of patients with ulcers, pernicious anemia, and the Zollinger-Ellison syndrome (peptic ulcer due to a gastrin-secreting tumor of the pancreas).

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2306, Jan. 14, 2000]

§ 862.1330 Globulin test system.

(a) *Identification*. A globulin test system is a device intended to measure globulins (proteins) in plasma and serum. Measurements of globulin are used in the diagnosis and treatment of patients with numerous illnesses including severe liver and renal disease, multiple myeloma, and other disorders of blood globulins.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in